



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,497	09/28/2001	Harry S. Sowden	MCP-294	5321
27777	7590	01/20/2004	EXAMINER ORTIZ, ANGELA Y	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT 1732	PAPER NUMBER

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,497

Applicant(s)

SOWDEN ET AL.

Examiner

Angela Ortiz

Art Unit

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-137 is/are pending in the application.
- 4a) Of the above claim(s) 23-136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 137 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 March 2002 and 29 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of claims 1-22, 137 on 24 October 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 23-136 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the response of 24 October 2003.

Claim Objections

Claim 137 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 137 refers to non-elected claim 24 in the alternative; reference to claim 24 should be deleted.

Specification

The disclosure is objected to because of the following informalities: page 21, line 27 includes a blank where information should be inserted; applicant is required to fill in the missing information. Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The title should be limited to the elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-10, 137 are rejected under 35 U.S.C. 102(b) as being anticipated by Dong et al., USP 5,830,502.

The cited reference teaches the claimed process of manufacturing an injection molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition for injection molding, forming the composition into pellets and loading the pellets into an injection molding machine. The injection molding machine conventionally includes a mold cavity, injection nozzle, and heating and cooling means. The composition for the dosage form may comprise a medicament. The molding machine heats the pellets to produce a flowable material, and the material is injected into a mold cavity until the mold is filled, and the composition is solidified into the shape of the cavity. Please see the abstract, col. 3, lines 45-65; col. 4, lines 3-30; col. 5, line 3, col. 6, lines 15-20, 35; col. 7, line 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2-5, 11-13, 21, 137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al., USP 5,830,502.

The cited reference substantially teaches the basic claimed process of manufacturing an injection molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition for injection molding, forming the composition into pellets and loading the pellets into an injection molding machine. The injection molding machine conventionally includes a mold cavity, injection nozzle, and heating and cooling means. The composition for the dosage form

Art Unit: 1732

may comprise a medicament. The molding machine heats the pellets to produce a flowable material, and the material is injected into a mold cavity until the mold is filled, and the composition is solidified into the shape of the cavity. Please see the abstract, col. 3, lines 45-65; col. 4, lines 3-30; col. 5, line 3, col. 6, lines 15-20, 35; col. 7, line 1.

The cited reference does not teach cooling in the hardening step as claimed.

Note that the hot liquid of the melted pellets is around 100°C, and is injected into a 75°C mold cavity and by injecting hot material into a cooler mold, cooling is being performed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the step of cooling during hardening to solidify the melted material.

With respect to claims 2-5, 11, note that the heating and cooling performed includes conventional means; it would have been obvious to further include the conventional means claimed for achieving the desired temperature effect.

With respect to claims 12-13, see col. 4, lines 18-25; col. 2, lines 35-65, wherein a defect free product is a long-standing object in the art of making dosage forms.

Claims 14-20, 22, 137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al., USP 5,830,502 in view of Voss, USP 6,177,125.

The cited primary reference substantially teaches the basic claimed process of manufacturing an injection molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition for injection molding, forming the composition into pellets and loading the pellets into an injection molding

machine. The injection molding machine conventionally includes a mold cavity, injection nozzle, and heating and cooling means. The composition for the dosage form may comprise a medicament. The molding machine heats the pellets to produce a flowable material, and the material is injected into a mold cavity until the mold is filled, and the composition is solidified into the shape of the cavity. Please see the abstract, col. 3, lines 45-65; col. 4, lines 3-30; col. 5, line 3, col. 6, lines 15-20, 35; col. 7, line 1.

The cited primary reference does not teach the claimed step of placing an insert in the mold cavity prior to injecting.

The added reference teaches as conventional a method of making coated tablets that comprise a core, the method further including placing the core or insert in the mold cavity prior to complete molding of the tablet. The detailed steps include providing a coating composition in granulate form, adding a core to the granules and molding the composition into tablet form. One embodiment forms the process in a single step, while additional embodiments partially fill the mold, place the core within the mold and then completely fill the mold to form a coated tablet. Note that the core can be injected. See claims 1-21, col. 1, lines 48-57.

It would to add an insert prior to complete molding of the dosage form, in view of the added reference, when performing the process set forth in the primary reference, for forming an encapsulated tablet. Note that the primary reference prefers a liquid center fill; it would have been obvious to use a non-liquid fill in view of the added reference, for forming an encapsulated tablet in a single process step.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USP's 5200191; 5391378; 5464631; 6350398; 6423256; 6499984; 6669883.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Ortiz whose telephone number is 703-308-4446. The examiner can normally be reached on Monday-Thursday 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaanni can be reached on 703-305-5493. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


Angela Ortiz
Primary Examiner
Art Unit 1732

ao